

## **Exhibit M**

IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF MASSACHUSETTS

In Re: )  
PHARMACEUTICAL INDUSTRY ) CA No. 01-12257-PBS  
AVERAGE WHOLESALE PRICE ) MDL No. 1456  
LITIGATION ) Pages 1 - 57

MOTION HEARING  
BEFORE THE HONORABLE PATTI B. SARIS  
UNITED STATES DISTRICT JUDGE

United States District Court  
1 Courthouse Way, Courtroom 19  
Boston, Massachusetts  
May 17, 2007, 2:45 p.m.

LEE A. MARZILLI  
OFFICIAL COURT REPORTER  
United States District Court  
1 Courthouse Way, Room 3205  
Boston, MA 02210  
(617)345-6787

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1 APP E A R A N C E S:  
 2 For the Plaintiffs:  
 3 LAURIE A. OBEREMBT, ESQ., United States Department of  
 4 Justice, P.O. Box 261, Ben Franklin Station, Washington,  
 5 D.C., 20004.  
 6 GEORGE B. HENDERSON, ESQ., Assistant United States  
 7 Attorney, Office of the United States Attorney,  
 8 1 Courthouse Way, Boston, Massachusetts, 02210.  
 9 JAMES JOSEPH BREEN, ESQ., 5755 North Point Parkway,  
 10 Suite 39, Alpharetta, Georgia, 30022, for the Relator,  
 11 Ven-A-Care of the Florida Keys.  
 12 For the Defendants:  
 13 NEIL MERKL, ESQ. and PAUL F. DOYLE, ESQ.,  
 14 Kelley Drye & Warren, LP, 101 Park Avenue, New York,  
 15 New York, 10178, for the Defendant, Dey, LP.  
 16 MARTIN F. MURPHY, ESQ., Foley Hoag, LLP,  
 17 Seaport World Trade Center West, 155 Seaport Boulevard,  
 18 Boston, Massachusetts, 02210-2600, for the Defendant,  
 19 Dey, LP.  
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 21  
 22  
 23  
 24  
 25

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1 obviously not the new one, which was the statute of  
 2 limitations point.  
 3 MR. MERKL: Yes, your Honor, given the reality of  
 4 your decision, and also I am sensitive that the Court has  
 5 heard and decided many of these similar issues before, I  
 6 really plan to address the statute of limitations.  
 7 THE COURT: So while I'm assuming you want to  
 8 preserve these objections on some of these issues for the  
 9 record should there ever be an appellate need, I don't know  
 10 that we need to spend a huge amount of time here unless you  
 11 think I'm dead wrong and missed something. I often find that  
 12 these drug cases are so complicated. For example, the  
 13 question arose in my mind, I realized I didn't know whether  
 14 there was ever a certification filed in the Medicaid context,  
 15 you know, and I was searching through the briefs to see  
 16 whether just as a factual matter that was required, either as  
 17 a matter of law or fact. So I resolved that in the way that  
 18 I did, and there may be just things I'm wrong on, and I had  
 19 to do it in the context of the four corners of the  
 20 complaint. So short of that, though, I don't want you to  
 21 reargue the cause to be presented. I've heard it in every  
 22 single case, and I'm not in your court on that.  
 23 MR. MERKL: Yes, your Honor. I guess I assume that  
 24 everything in the papers is preserved.  
 25 THE COURT: Right.

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1 P R O C E E D I N G S  
 2 THE CLERK: In Re: Pharmaceutical Industry Average  
 3 Wholesale Price Litigation, Civil Action No. 01-12257,  
 4 MDL 1456, will now be heard before this Court. Will counsel  
 5 please identify themselves for the record.  
 6 MR. HENDERSON: Good afternoon, your Honor. George  
 7 Henderson, Assistant U.S. Attorney, and Laurie Oberembt for  
 8 the Department of Justice, who will argue the government's  
 9 case today.  
 10 MS. OBEREMBT: Good afternoon, your Honor.  
 11 THE COURT: All right, thank you.  
 12 MR. BREEN: Jim Breen. I represent the relator,  
 13 Ven-A-Care of the Florida Keys. Good afternoon.  
 14 MR. MURPHY: Good afternoon, your Honor. Martin  
 15 Murphy for the Defendant Dey with Neil Merkl from Kelly Drye  
 16 and Paul Doyle with Kelly Drye, and Mr. Merkl is going to  
 17 argue the case for Dey today.  
 18 THE COURT: Sounds good.  
 19 MR. MERKL: May I proceed?  
 20 THE COURT: Yes.  
 21 MR. MERKL: Thank you. Your Honor --  
 22 THE COURT: Before you do, I realize I just issued  
 23 it, but I actually issued an opinion about a week ago --  
 24 MR. MERKL: Yes, your Honor.  
 25 THE COURT: -- resolving some of these issues but

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1 MR. MERKL: And what you'd like to hear about is  
 2 perhaps something you haven't heard about before.  
 3 THE COURT: Unless you think I was just dead wrong  
 4 literally factually kind of thing; you know, as it turns out,  
 5 there in fact is no certification at all in Medicaid, and it  
 6 isn't required as a matter of law, you know, or -- you know,  
 7 something that's just so basic to the decision.  
 8 MR. MERKL: Okay, I think I have it.  
 9 THE COURT: Okay.  
 10 MR. MERKL: We may have a wrinkle like that on some  
 11 of the issues but not many, but really I think the statute of  
 12 limitations --  
 13 THE COURT: The statute seems like a big new issue,  
 14 and we should resolve it because I read with interest the  
 15 Second Circuit opinion. I hadn't seen it before you flagged  
 16 it for me. And I've read two or three follow-on District  
 17 Court cases, the District of Columbia and the State of  
 18 Washington. I think those were the two major ones.  
 19 MR. MERKL: Those are the two that I've seen, your  
 20 Honor. Well, then let me start there.  
 21 THE COURT: Okay.  
 22 MR. MERKL: The case against Dey was unsealed in  
 23 August of '06 and served in September, and our contention is  
 24 that any claim arising under the False Claims Act is barred  
 25 by the six-year statute, which means anything prior to August

2 (Pages 2 to 5)

<p>1 of '06 is barred, okay?</p> <p>2 THE COURT: Can I start. I believe the judge --</p> <p>3 and I met him, so I'm embarrassed I'm not remembering his</p> <p>4 name -- the judge from Florida I think called me.</p> <p>5 MR. BREEN: Judge Gold, your Honor?</p> <p>6 THE COURT: Yes. And the one thing as I was</p> <p>7 preparing yesterday I didn't have is, have you ever seen the</p> <p>8 original complaint?</p> <p>9 MR. MERKL: Well, it depends what you mean by</p> <p>10 original complaint.</p> <p>11 THE COURT: The complaint filed initially.</p> <p>12 MR. MERKL: There's a 1995 original complaint we</p> <p>13 have heard about that I don't believe we've been provided by</p> <p>14 the government. Dey is not in that complaint, unless I'm</p> <p>15 mistaken, okay.</p> <p>16 MS. OBEREMBT: That's correct.</p> <p>17 MR. MERKL: And from what I understand, in 1997</p> <p>18 there was a subsequent iteration or amendment of that</p> <p>19 complaint. Dey was added in that complaint.</p> <p>20 THE COURT: Is that right?</p> <p>21 MS. OBEREMBT: Yes, your Honor, that's correct.</p> <p>22 THE COURT: Didn't I order all this disclosed, or</p> <p>23 was it another case? I'm so confused on all my Ven-A-Care</p> <p>24 cases.</p> <p>25 MS. OBEREMBT: Your Honor, we provided redacted</p>	<p>Page 6</p> <p>1 THE COURT: Okay, so the only one that sort of</p> <p>2 routes back to 1997 that's been consistently in there is the</p> <p>3 albuterol?</p> <p>4 MR. MERKL: Well, again, when you say consistently</p> <p>5 in there, it was certainly in that; and in the subsequent six</p> <p>6 intervening amended complaints, I don't know whether</p> <p>7 albuterol was in each of those. There were two drugs added</p> <p>8 later.</p> <p>9 THE COURT: Well, was it?</p> <p>10 MS. OBEREMBT: I believe albuterol was in all of</p> <p>11 those, and if you recall, your Honor, there's also --</p> <p>12 Ven-A-Care filed a complaint in Boston against Dey in 2000</p> <p>13 which added additional drugs. There are essentially three</p> <p>14 drugs at issue here: albuterol, cromolyn sodium, and</p> <p>15 ipatropium bromide.</p> <p>16 MR. MERKL: And we agree with that.</p> <p>17 MR. BREEN: Your Honor, I could give you the exact</p> <p>18 drugs in the '97 complaint if counsel --</p> <p>19 THE COURT: The '97 complaint with Dey is what?</p> <p>20 MR. BREEN: I'm looking at them right now, your</p> <p>21 Honor, and they are -- the albuterols are in there, albuterol</p> <p>22 sulfate. Also I believe acetylcystine, acetylcystine</p> <p>23 solution is in here, and the other one is the other</p> <p>24 acetylcystine solution. Metaproterenol sulfate, 4/10 of a</p> <p>25 percent, is in there, sodium chloride. And later, your</p>
<p>Page 7</p> <p>1 versions of every complaint in which Dey was named as the</p> <p>2 defendant to Dey.</p> <p>3 THE COURT: Okay, so you don't mean "today"?</p> <p>4 MS. OBEREMBT: No, no.</p> <p>5 THE COURT: A while ago --</p> <p>6 MS. OBEREMBT: Yes, your Honor.</p> <p>7 THE COURT: -- you gave them to the defendants.</p> <p>8 MS. OBEREMBT: Absolutely, your Honor.</p> <p>9 THE COURT: All right. So is it correct that in</p> <p>10 the 1995 complaint, Dey was not mentioned at all; and the</p> <p>11 first time that the United States brought a claim or the</p> <p>12 relator brought a claim -- is it the relator or the United</p> <p>13 States?</p> <p>14 MS. OBEREMBT: The relator brought the claim</p> <p>15 initially on behalf of the United States against Dey in 1997.</p> <p>16 THE COURT: In 1997, that was a relator complaint?</p> <p>17 MS. OBEREMBT: Yes, your Honor.</p> <p>18 THE COURT: And did it include every drug at issue</p> <p>19 here today?</p> <p>20 MS. OBEREMBT: No, it did not, your Honor.</p> <p>21 THE COURT: So which drugs did it include?</p> <p>22 MR. MERKL: Albuterol is the only one, I believe,</p> <p>23 that was in that that is still in this. There might have</p> <p>24 been saline or acetylcystine or something that was in that</p> <p>25 but is not now in this case, unless I'm mistaken.</p>	<p>Page 9</p> <p>1 Honor, I believe in a later complaint -- and I could go</p> <p>2 through it during the hearing -- I think cromolyn was added</p> <p>3 in a later amendment in Florida.</p> <p>4 THE COURT: What was that drug?</p> <p>5 MR. BREEN: Cromolyn.</p> <p>6 THE COURT: C-R --</p> <p>7 MR. BREEN: C-h-r-o-m-y-l-i-n, I believe.</p> <p>8 MR. MERKL: I think that's right.</p> <p>9 THE COURT: Now, the reason I ask this is the</p> <p>10 obvious one, and there are different ways of thinking about</p> <p>11 this. If I went with the Second Circuit all the way, this</p> <p>12 wouldn't matter --</p> <p>13 MR. MERKL: That's correct.</p> <p>14 THE COURT: -- to some extent. But if you did a</p> <p>15 relation back and I accepted it, it's relation back to what?</p> <p>16 So, like, if Dey wasn't in the 1995 one at all, it wouldn't</p> <p>17 be part of the analysis for whether it was the same</p> <p>18 transaction/occurrence because it wasn't the same company,</p> <p>19 but it could go back to 1997 if in fact it was the same</p> <p>20 drugs.</p> <p>21 So, in other words, I'm not sure I agree with</p> <p>22 Judge Jacobs all the way, but I may agree with him in part,</p> <p>23 and so that's why I'm trying to understand what was added</p> <p>24 when. Remember, he says that subpart -- now, we're not</p> <p>25 addressing the issue of whether or not by statute it relates</p>

<p>1 back --</p> <p>2 MR. MERKLY: Your Honor is right --</p> <p>3 THE COURT: -- the first prong, right? And so</p> <p>4 assuming that there is a relation-back component to it, it's</p> <p>5 got to be relating back to the same transaction -- what are</p> <p>6 the words, the transaction --</p> <p>7 MR. MERKL: Or occurrence. Also, your Honor, if</p> <p>8 there is going to be relation back, our position would be, it</p> <p>9 can only relate back to a valid complaint. And let me give</p> <p>10 you an example. Apparently the first False Claims Act</p> <p>11 qui tam cases against Dey were filed in Florida. There was a</p> <p>12 qui tam proceeding. And then later on they started a new one</p> <p>13 in Massachusetts that was unrelated.</p> <p>14 Well, in our view, under the bar rule, the (B)(5)</p> <p>15 bar rule of the False Claims Act, they can't do that. Once</p> <p>16 there's a False Claims Act pending involving the same facts</p> <p>17 and circumstances, a relator can't start a related case in</p> <p>18 another jurisdiction. And that has been held, the bar rule,</p> <p>19 to divest courts of subject matter jurisdiction. So right</p> <p>20 off the bat, if we're talking about these multiple complaints</p> <p>21 relation back --</p> <p>22 THE COURT: Well, what came first, Florida or</p> <p>23 Massachusetts?</p> <p>24 MR. MERKL: Florida, your Honor. Massachusetts</p> <p>25 started, I believe, in 2000.</p>	<p>Page 10</p> <p>1 same -- I should have brought the rule down, but transaction</p> <p>2 or occurrence.</p> <p>3 MR. MERKL: Actually, your Honor, Judge Jacobs said</p> <p>4 that there couldn't be relation back at all.</p> <p>5 THE COURT: I know he did, but I'm not sure I agree</p> <p>6 with that. I mean, neither did the subsequent two District</p> <p>7 Courts say, and so I'm working it through. The opinion</p> <p>8 actually shocked me. I must say I've, as Mr. Henderson</p> <p>9 knows, been a persistent burr under the saddle of the United</p> <p>10 States Attorney's office here, and I won't let them go past</p> <p>11 two or three years. They're now going to be thanking me. I</p> <p>12 don't know if you had the case, but, I mean, I at some point</p> <p>13 pulled the plug on Neurontin. I said, "I'm not waiting any</p> <p>14 longer." And so, I mean, I was even surprised it went as</p> <p>15 long as it did, I have to tell you.</p> <p>16 But right now I've got that fact situation, and</p> <p>17 that doesn't mean that if I agree with him that the</p> <p>18 relation-back doctrine applies, or at least if I -- I think I</p> <p>19 need to think about what was in the original complaint, what</p> <p>20 was in the next complaint, when does it relate back, and what</p> <p>21 does that do vis-a-vis the statute of limitations, right?</p> <p>22 MR. MERKL: Yes.</p> <p>23 THE COURT: So if in 1997 there was a relator</p> <p>24 complaint against Dey for at least -- let's start with these</p> <p>25 four drugs -- why wouldn't the complaint in intervention</p>
<p>Page 11</p> <p>1 THE COURT: But if these were added in 1997 in</p> <p>2 Florida, why wouldn't Florida come first?</p> <p>3 MR. MERKL: Well, correct, your Honor, Florida</p> <p>4 would come first, and what we --</p> <p>5 THE COURT: And that would bar Massachusetts.</p> <p>6 MR. MERKL: And that would bar any subsequent</p> <p>7 proceeding in Massachusetts, that's correct.</p> <p>8 THE COURT: It's not a real win for you. I've got</p> <p>9 them all. For me, it's just which pot it gets put in.</p> <p>10 MR. MERKL: Right, but to the extent, though,</p> <p>11 there's a claim that they're trying to have relation back for</p> <p>12 that's in today's complaint, it can't relate back to a</p> <p>13 Massachusetts complaint if that wasn't a proper complaint to</p> <p>14 begin with.</p> <p>15 THE COURT: But it can relate back to a Florida</p> <p>16 complaint.</p> <p>17 MR. MERKL: If it was in a Florida complaint. But</p> <p>18 what if it's a new drug? What if it's a different sale?</p> <p>19 THE COURT: Well, that's what I'm trying to figure</p> <p>20 out. That's precisely the point. If I don't go all the way</p> <p>21 with Judge Jacobs -- and I read it with huge amount of</p> <p>22 interest. He basically barred it all. If I did accept the</p> <p>23 relation back under that first-prong doctrine, what do I do</p> <p>24 with the fact that there are new companies and new drugs?</p> <p>25 Because relation back has to be a relation back to the</p>	<p>Page 13</p> <p>1 relate back to 1997?</p> <p>2 MR. MERKL: For the reasons Judge Jacobs explained</p> <p>3 in Baylor.</p> <p>4 THE COURT: Because you would say there was no</p> <p>5 notice?</p> <p>6 MR. MERKL: There was no notice. Can I tell you</p> <p>7 why I think he's right?</p> <p>8 THE COURT: Okay.</p> <p>9 MR. MERKL: Okay.</p> <p>10 THE COURT: In fact you had notice, right, at that</p> <p>11 point right because it was all unsealed and you were told</p> <p>12 about it?</p> <p>13 MR. MERKL: Well, we were told there was a</p> <p>14 proceeding, but we didn't have notice in the sense that --</p> <p>15 THE COURT: I thought it was unsealed.</p> <p>16 MR. MERKL: No, no, no.</p> <p>17 THE COURT: The partial unsealing, when was that?</p> <p>18 MR. MERKL: I think they showed us the complaint,</p> <p>19 but -- yes, but, all right, well, let me explain why that's</p> <p>20 not notice. All right, the reason it's not notice, your</p> <p>21 Honor, is because we couldn't litigate the case. We couldn't</p> <p>22 take the government's testimony.</p> <p>23 THE COURT: Well, but those are two separate</p> <p>24 issues, notice and not being able to preserve testimony.</p> <p>25 MR. MERKL: But the Second Circuit, your Honor, had</p>

<p>1 the same facts in front of it. In the Baylor case, that case  2 went back eight or nine years. The defendants had been shown  3 the complaint. The defendants had litigated some ancillary  4 issues in California trying to get some of the rule changes  5 challenged, and that wasn't good enough. What you have to  6 have is a complaint served on you that you can litigate to  7 protect your position.</p> <p>8 And the reason that's especially important in a  9 case like this is, if you go back to 1995 when all this  10 starts, the government from between 1995 and 2000 I think  11 served about five different subpoenas on Dey. All Dey's  12 employees who basically were accused of being involved in  13 this conduct, they were all long gone. We're taking  14 depositions now today of people at OIG; and when you put  15 these reports that your Honor has heard so much about in  16 front of them and you ask them questions about the report,  17 they don't remember. So there really is substantial  18 prejudice from the litigation standpoint.</p> <p>19 THE COURT: What you don't need to remember that's  20 out there, that in 1996 they knew the spreads on albuterol  21 were huge.</p> <p>22 MR. MERKL: Well, the question then is, well, why  23 didn't you --</p> <p>24 THE COURT: But all you've got is albuterol. It  25 doesn't help you with the other drugs, right?</p>	<p>1 brief, it's very clear that in 1986 when Congress sat down to  2 look at the statute, they had a couple of concerns, all  3 right? One concern was, well, what if a relator comes in on  4 the eve the statute of limitations is going to expire, and  5 there's no time to investigate, we can't address this, what  6 can we do? So they put a three-year toll on the statute.</p> <p>7 So the relator comes in with a complaint. Congress  8 decided that the way to deal with this short window of  9 opportunity is to give the government a three-year toll.</p> <p>10 They ameliorated the six-year statute. That's what they gave  11 the government.</p> <p>12 Now, the same report also talks about the seal.</p> <p>13 Why do we have the seal? Well, the report says the reason  14 for the seal is --</p> <p>15 THE COURT: So help me through how that works. So  16 let's assume I say there's a -- let's forget the 1995  17 complaint because you're not mentioned -- there's a 1997  18 against Dey.</p> <p>19 MR. MERKL: Yes, your Honor.</p> <p>20 THE COURT: And normally everything would have to  21 have been -- you would say that that, what, was tolled for  22 three years, the statute of limitations, to 2000?</p> <p>23 MR. MERKL: Yes. I would say, I guess, the  24 relator comes in --</p> <p>25 THE COURT: The government should have brought suit</p>
<p>1 MR. MERKL: In the report -- well, ipotropium I  2 believe is the subject of a report.</p> <p>3 THE COURT: Is that that famous, in my world,  4 famous 1996 OIG report that had that other drug in it?</p> <p>5 MS. OBEREMBT: No, I don't believe so, your Honor.</p> <p>6 MR. MERKL: No, there's a different report about  7 ipotropium. There's the 1996 about albuterol. There's a  8 '97 report was about --</p> <p>9 THE COURT: Who did that, OIG?</p> <p>10 MR. MERKL: Yes.</p> <p>11 MS. OBEREMBT: I believe the other drugs appear  12 much later than albuterol.</p> <p>13 MR. MERKL: That's true, it's later. Albuterol is  14 the earliest.</p> <p>15 MS. OBEREMBT: Right. And in the earliest report,  16 the spreads they're talking about are between 20 and  17 30 percent, so they're much less than what we have in our  18 complaint.</p> <p>19 THE COURT: I thought albuterol was higher than  20 that in --</p> <p>21 MS. OBEREMBT: Not in the early reports, no.</p> <p>22 MR. MERKL: Your Honor, the reason, though, the  23 Second Circuit view of this is correct, though, really goes  24 back to the language of the statute. And if you look at the  25 language and the Senate report that we cite to you in the</p>	<p>1 by 2000?</p> <p>2 MR. MERKL: Yes. The relator comes in with a  3 complaint. Assuming the government had no inkling or  4 knowledge of this, there's no issue of the government's prior  5 knowledge which could trigger the six-year statute, assuming  6 the government knows nothing, they either get the full six or  7 they get three years from notice to file a case. So even if  8 those claims are going to go stale and the relator comes in  9 at midnight, if the truth of the matter is the government  10 didn't know, what this tolling provision is, it gives the  11 government three years. So the whole idea that they would  12 have to drop everything, they couldn't make an informed  13 decision that drives a lot of these decisions allowing  14 relation back, that really isn't correct.</p> <p>15 The 60-day seal provision that they talk about in  16 the same report, your Honor, is for something different. The  17 60-day seal provision arises out of concerns that, well, what  18 if the government is already looking at this? What if  19 there's a criminal investigation or some kind of secret  20 investigation going on? We don't want to have some relator  21 willy-nilly going into court and tipping the defendant, so it  22 has to be under seal, it has to be 60 days. Now --</p> <p>23 THE COURT: I actually thought it was to protect  24 the defendant.</p> <p>25 MS. OBEREMBT: That's right, your Honor, one of the</p>

<p>1 key purposes is to protect the defendant from accusations 2 that turn out not to be true.</p> <p>3 MR. MERKL: The reason I just gave you is in the 4 Senate report. It's to prevent in part tipping that off. 5 It's also to allow the government time to take a look at the 6 complaint and decide, does the government want to intervene? 7 But it's different from the idea of the eleventh-hour claim. 8 When Congress talked about that, they also talked about it 9 differently. Congress said the seal provision, in the 10 legislative history that we quote in the brief, is not 11 intended to adversely affect the defendant's rights.</p> <p>12 Now, if you're going to allow the seal provision to 13 basically swallow the statute by allowing the government to 14 come in and extend the statute of limitations beyond that 15 three years to eight, nine, ten, years like we have in this 16 case, you've basically given the government the right to 17 unilaterally avoid the statute. And I submit that if you 18 take a look at that Senate report, that is absolutely not 19 what Congress intended. Congress said when they enacted --</p> <p>20 THE COURT: Although there is an ambiguity because 21 they don't put a limit on the number of extensions.</p> <p>22 MR. MERKL: Well, that's true. On the other hand, 23 when you read -- and I'm not saying that it's limited. I am 24 saying that they're two different things. The government is 25 given three years toll, right? And they're given a 60-day</p>	<p>1 this reason or that reason," the government is taking that 2 risk. I don't -- well, I don't know what the district judge 3 is doing, but I don't think, and it's not represented in the 4 papers, that the district judge is making evaluations about 5 the statute of limitations. That's the government's call. 6 They're the litigant. So if they're going to stretch this 7 thing out for three and four years, that's a risk they're 8 taking.</p> <p>9 THE COURT: Have you gotten all those documents? 10 Was it your case I unsealed all of them?</p> <p>11 MR. MERKL: No, but we'd like them.</p> <p>12 THE COURT: Whose case did I unseal them for?</p> <p>13 MS. OBEREMBT: That issue has come up in the Abbott 14 litigation, but it's undoubtedly going to affect this case 15 also.</p> <p>16 THE COURT: Because they get them, unless it's 17 something, you know, like an informant or something like 18 that, you know, some secret strategy involving a potential 19 criminal case. I get tons of these, by the way. We're like 20 the qui tam capital of the world here. I get tons of these. 21 So sometimes it actually is confidential, but most of the 22 times it isn't, so --</p> <p>23 MS. OBEREMBT: I completely understand your Honor's 24 point on that.</p> <p>25 THE COURT: So just look through them and give them</p>
<p>1 seal. Now, after that 60 days is up, the government has to 2 make the same value judgments that any other litigant has to 3 make. They have X number of years left on the statute, do 4 they keep it sealed, how quickly and aggressively do they 5 investigate it? This 60-day rule was not meant to shield 6 them from that, to give them indefinite extension of the 7 statute. It's just not in the legislation. In fact, it's 8 really contrary to it when you see that the seal is put in at 9 the same time the toll is put in. Why do you need the toll?</p> <p>10 THE COURT: Suppose, though, I have a Federal 11 District Court judge in Florida who thought there was good 12 cause. So essentially you would be saying that no matter how 13 good the cause, it can't trump the tolling?</p> <p>14 MR. MERKL: Exactly, your Honor. I'm saying it's 15 really two different things.</p> <p>16 THE COURT: In other words, you get as many 60-day 17 extensions as you can get up to the tolling?</p> <p>18 MR. MERKL: I'm saying that if the government 19 really wants to go and keep tolling it -- I'm sorry -- if the 20 government wants to keep it secret and the government meets 21 the criteria for keeping it secret, that that's a different 22 thing from the tolling. The three years is the three years. 23 They have to live with that. So if they go into a district 24 judge and they tell the district judge, "We have this 25 proceeding going on, we need to keep it secret," or, "We have</p>	<p>1 whatever isn't going to a criminal case or something like 2 that.</p> <p>3 MS. OBEREMBT: I believe Assistant U.S. 4 Attorney Levine in Florida is actually --</p> <p>5 THE COURT: Cursing me as we speak, right?</p> <p>6 MS. OBEREMBT: Well, praying to whatever deity he 7 prays to right now.</p> <p>8 THE COURT: I hear you. All right, go ahead.</p> <p>9 MR. MERKL: So the Second Circuit decision really 10 is the decision that's correctly in line with the legislative 11 history here. The prior decisions, the unreported ones and 12 Downey and some of the other ones that we see all the time, 13 they're based on the mistaken impression that the government 14 has to act before midnight with this seal within 60 days, 15 when they don't. The government has three years to make up 16 their mind. And what we're saying is that you can't take the 17 60-day seal provision and indefinitely stretch that out. 18 Otherwise you are affecting the defendants' rights adversely.</p> <p>19 THE COURT: If I dealt with it more as a classic 20 relation back, the statute doesn't -- I think the word used 21 was that, you know, after a certain period of time the 22 government can "take over" the case, those are the words, 23 "take over."</p> <p>24 MR. MERKL: Yes.</p> <p>25 THE COURT: And so I think it's been my experience,</p>

<p>1 which is borne out in the treatises, that in practice what  2 happens is, they draft their own complaint in intervention in  3 a separate --</p> <p>4 MR. MERKL: That's what happened here, your Honor.</p> <p>5 THE COURT: That's not something that was  6 specifically mentioned in the statute. It's just in  7 practice, that's what happens. It happened in every single  8 one of my cases where the government chose to intervene, and  9 I'm assuming that's national because the treatise says it's  10 what they do.</p> <p>11 So why wouldn't I just treat that under the  12 relation-back doctrine? In other words, it sounds like  13 they're out of the loop in terms of 1995 because they didn't  14 mention you there, but let's assume they mentioned you in  15 1997. Why wouldn't this just relate back to 1997 under the  16 second prong, first and second prong, if it involved the same  17 transaction/occurrence and on and on?</p> <p>18 MR. MERKL: Because Rule 15(c) can't be applied  19 here for the reasons that the Second Circuit gives.</p> <p>20 THE COURT: Well, suppose I don't buy that all the  21 way, the second fall-back would be, at the very least, they  22 can't be adding any new drugs and --</p> <p>23 MR. MERKL: Well, they certainly can't do that.  24 And I also would say that then you'd be left with a situation  25 where if you didn't allow the relation back, even those</p>	<p>1 Second Circuit did, it said, well, why does it have to be the  2 same facts and circumstances? Why can't it be something  3 else? And the reason for that is fairness to the defendant.  4 If it is the same facts and circumstances and if  5 the case is three or four years old, those are facts and  6 circumstances and claims the parties have been litigating and  7 living with, and there's some basis to assume that the  8 evidence is preserved, that the defendant isn't surprised,  9 that it's not stale. That's why 15(c) itself depends on it  10 being the same facts and circumstances. If you remove --</p> <p>11 THE COURT: If you win this, you don't win the  12 whole day, right, because you at least go back to -- when was  13 this filed? -- you still have claims by then from 2000 to  14 2006, right? I mean, this is just a partial victory if I  15 adopt the Second Circuit.</p> <p>16 MR. MERKL: Well, not necessarily.</p> <p>17 THE COURT: Why?</p> <p>18 MR. MERKL: Not necessarily. Under Rivera clearly,  19 I think, in the First Circuit, every claim submitted up until  20 that date would be out, all right? Based on the complaint  21 the way it's pled today, the wrongful conduct they've accused  22 Dey of concerns three drugs where the AWPs were set before  23 2000.</p> <p>24 THE COURT: I don't accept that.</p> <p>25 MR. MERKL: Okay.</p>
<p>1 courts -- for instance, the District of Arkansas decision in  2 St. Joseph's, and then there was a decision up here in the  3 District of Massachusetts -- even those courts that appear to  4 have allowed some form of relation back, they say you can  5 only relate back to a valid complaint. And our view is then,  6 once we get the complete file, we're permitted to go back and  7 take a look: Was the relator really an original source? Did  8 the court really have subject matter jurisdiction? Was it  9 properly pled?</p> <p>10 One of the decisions that we've seen, and again  11 this is, I think, the St. Joseph's case, is the court said --</p> <p>12 THE COURT: But I don't have that now. I'm at the  13 very threshold level of this very interesting Baylor case,  14 which I never knew about until you brought it to my  15 attention, and it's very interesting. I mean, it reflects  16 some of the exasperation I've felt with these on and on and  17 on extensions. On the other hand, I don't know -- I mean,  18 they just seem to apply a meat cleaver, and I just wondered  19 whether there was a more nuanced approach here.</p> <p>20 MR. MERKL: Well, I think, your Honor, what has  21 really happened is, Baylor is the first court that looked at  22 Rule 15 straight up and said, well, the other courts kind of  23 applied it in this knee-jerk fashion where it's, well,  24 Rule 15 says, as long as it's the same facts and  25 circumstances, they can relate back, all right? What the</p>	<p>1 THE COURT: Okay? You've preserved it. It's every  2 time the claim, it's a continuing tort. I mean, good try, I  3 mean, but let me just -- it was an interesting --</p> <p>4 MR. MERKL: You're going to save me the time on  5 that one, okay.</p> <p>6 THE COURT: Yes.</p> <p>7 MR. MERKL: All right, well, Bornstein is my  8 argument on that, your Honor, and if --</p> <p>9 THE COURT: I understand.</p> <p>10 MR. MERKL: But, still, cutting off at --</p> <p>11 THE COURT: If they only published the AWP once,  12 you might have a running try, but they do it every quarter.  13 By the way, I know this a little bit more than I want to.  14 So, I mean, it's a continuing tort, it's continuing wrongful  15 conduct, allegedly.</p> <p>16 MR. MERKL: But still, your Honor, that still  17 substantially cuts the case back and limits the conduct. At  18 least then we're talking about six years' worth of conduct  19 and not fifteen years.</p> <p>20 THE COURT: I understand that. I'm with you. I'm  21 just simply saying, it doesn't make this case go away.</p> <p>22 MR. MERKL: Well, I don't know, I just don't know,  23 because the spreads change over time, what's happened here,  24 how we report.</p> <p>25 THE COURT: You're just saying factually it might</p>

<p>1 make a difference.</p> <p>2 MR. MERKL: Well, factually, I guarantee it will</p> <p>3 make a huge difference. How big? Does it effectively make</p> <p>4 the case go off your docket? No, I can't represent that to</p> <p>5 you.</p> <p>6 THE COURT: I'm unlikely to dismiss it on a 1996</p> <p>7 albuterol study on a motion to dismiss, although it may be an</p> <p>8 appropriate summary judgment motion.</p> <p>9 MR. MERKL: Yes.</p> <p>10 THE COURT: Was there any other threshold-type</p> <p>11 issue?</p> <p>12 MR. MERKL: One issue on the -- you mean, apart</p> <p>13 from the statute of limitations?</p> <p>14 THE COURT: Yes, big issue, big new issue.</p> <p>15 MR. MERKL: As a component of 9(b), okay, one of</p> <p>16 the problems with the government's complaint, what it leaves</p> <p>17 vague, is what money are they suing for? Do they want the</p> <p>18 state share for each one of the 50 states? Do they want the</p> <p>19 federal share for each one --</p> <p>20 THE COURT: This is for the Medicaid drugs?</p> <p>21 MR. MERKL: For Medicaid, that's right, your Honor,</p> <p>22 I'm just talking about the Medicaid claims. Do they want the</p> <p>23 federal share --</p> <p>24 THE COURT: They're suing for both programs,</p> <p>25 though, right? I'm sorry. They're suing for both programs,</p>	<p>Page 26</p> <p>1 THE COURT: But I have it, right?</p> <p>2 MR. MERKL: You have that one, okay.</p> <p>3 THE COURT: And I know I'm thinking about the</p> <p>4 Montana/Nevada Medicaid. Does that involve you?</p> <p>5 MR. MERKL: No. We're out of that --</p> <p>6 MR. BREEN: Your Honor, what about -- let's talk</p> <p>7 about Florida. It's the Ven-A-Care case, False Claims Act</p> <p>8 case against Dey Laboratories in Florida.</p> <p>9 THE COURT: That's a state case?</p> <p>10 MR. BREEN: A state case. Well, I think it's</p> <p>11 before your Honor on another removal, but it hasn't gone back</p> <p>12 yet, but there's been a bunch of removals.</p> <p>13 THE COURT: You just confirmed that. There are,</p> <p>14 like, twelve removals that have come up again after Grable.</p> <p>15 Okay, but how are we parsing out, because for sure there</p> <p>16 shouldn't be double recovery?</p> <p>17 MR. BREEN: Absolutely. I don't want to jump into</p> <p>18 his argument, your Honor, but I definitely have a response to</p> <p>19 that question. But I just want to suggest we talk about</p> <p>20 Florida because it will help bring the issue --</p> <p>21 MR. MERKL: Well, that's why we removed Florida</p> <p>22 because there should be one case. The Florida case should be</p> <p>23 either stopped in the state pending this one, or combined,</p> <p>24 and it should be tried in one court with the other states.</p> <p>25 THE COURT: You know, it's interesting because I've</p>
<p>1 right?</p> <p>2 MS. OBEREMBT: Yes, your Honor.</p> <p>3 MR. MERKL: Well, they're suing for both programs.</p> <p>4 But on the Medicaid side of this, do they want Dey to pay the</p> <p>5 federal government share for 50 states, the federal</p> <p>6 government and the state share for all 50 states, some</p> <p>7 combination in between? Because as your Honor is aware, we</p> <p>8 have state Medicaid cases out there that, in our view, if</p> <p>9 there is any overlap at all with these dollars, they're</p> <p>10 barred by the bar rule. You can't have a related case out</p> <p>11 there in the state seeking the same money that the federal</p> <p>12 government is trying to claim in this case.</p> <p>13 THE COURT: Well, that's a complicated question</p> <p>14 because I have all the diversity cases but not the nondiverse</p> <p>15 cases, so I don't know what's happening. Is there any</p> <p>16 particular case you're worried about? In other words --</p> <p>17 MR. MERKL: We worry about them all, your Honor,</p> <p>18 but, for instance, in Alaska --</p> <p>19 THE COURT: I mean, I can do it back here, I</p> <p>20 think. You know, I'm like the puppeteer here, but I can't</p> <p>21 deal with the ones that are back in state court. Is there a</p> <p>22 particular case that you're worried about?</p> <p>23 MR. MERKL: Well, California, your Honor. Why</p> <p>24 should the California qui tam go separately? Shouldn't that</p> <p>25 be one case with this one?</p>	<p>Page 27</p> <p>1 been struggling with that after Grable, which I think tilts</p> <p>2 the balance towards Federal Court for the Medicare cases, but</p> <p>3 I wasn't sure about the Medicaid cases.</p> <p>4 MR. MERKL: Well, your Honor, you know, on Medicaid</p> <p>5 typically you're stuck, but here it's different because here</p> <p>6 there is a federal Medicaid claim brought under the False</p> <p>7 Claims Act, which we contend allowed us to remove it to the</p> <p>8 Federal Courts, but we haven't been as successful as we'd</p> <p>9 like so far. But nevertheless we still have that bar rule.</p> <p>10 We think we should be able to go to state court and stop</p> <p>11 those. But the reason that I think it's significant for your</p> <p>12 Honor, though --</p> <p>13 THE COURT: Well, that's a significant issue. You</p> <p>14 raised it here, I think. Someone did.</p> <p>15 MR. MERKL: Yes, but what's happening, though, is,</p> <p>16 you go to state courts and it's not clear. I mean, they'll</p> <p>17 say, well, that's just the federal share, or they don't want</p> <p>18 this money. The complaint I'm suggesting is vague. I'm</p> <p>19 suggesting the complaint needs to specify what it is they're</p> <p>20 claiming.</p> <p>21 THE COURT: Do you want both halves, the federal</p> <p>22 and the state half?</p> <p>23 MR. BREEN: In Florida?</p> <p>24 THE COURT: Here.</p> <p>25 MR. BREEN: Here? No. In Florida, absolutely.</p>

<p>1       THE COURT: Let me ask Uncle Sam for a minute.  2       MS. OBEREMBT: Sure. Your Honor, we believe under  3 the False Claims Act, we can only seek recovery of the  4 federal share.  5       THE COURT: Okay, there it is.  6       MR. MERKL: For all fifty states?  7       THE COURT: Well, no, they're going to take  8 Arkansas, a hundred percent and -- of course all fifty.  9       MS. OBEREMBT: Right, I don't think we can pick and  10 choose.  11      THE COURT: Only federal share.  12      MR. BREEN: Your Honor, if I could just briefly --  13      THE COURT: Yes, let me just -- so is that the only  14 other? Let me finish him. Then I'll let you pop up.  15      MR. MERKL: And that issue is a big help, but the  16 states, however, don't view it that way. The states are  17 claiming they can collect.  18      THE COURT: I know. For my motion to dismiss  19 purposes, I'm just -- I've got so many of these cases, I've  20 got blinders on. I do them one by one. So for this motion  21 to dismiss, are there any novel issues other than the statute  22 of limitations that I haven't addressed in one of my previous  23 decisions?  24      MR. MERKL: I think one other, and it's a pleading  25 issue, and it touches on something you were talking about in</p>	<p>1 there yesterday, but we had every county in New York now  2 suing here, and so -- and it's come up in other cases too  3 where I've been unsure about the impact of the FUL in this  4 litigation because it's not a direct derivative of AWP, which  5 is something I'm familiar with. So I don't know that you  6 need to start there. That's not the key threshold issue, but  7 if you want --  8        MR. BREEN: I can cover it real quickly your Honor,  9 I think, and that's why Ms. Oberembt asked me to respond to  10 that particular issue. I mean, these two issues are hanging  11 out there, double collection, as the defendants call it, or  12 bar rule, and the impact of the FUL. And, quite frankly,  13 Ven-A-Care, who's got cases here in these federal cases and a  14 lot of these state cases, have never really been in a  15 position to answer the question, from our perspective. It  16 might help.  17      Number one, as far as the FUL goes, the way we've  18 pled this federal case and the way we've pled every one of  19 our state cases, it's an issue of damage. If a Federal Upper  20 Limit was set, then the damage that we seek is the amount  21 that should have been paid had a nonmisleading price resulted  22 in a reimbursement less than the FUL. So it's a damages  23 issue.  24      THE COURT: It's liability too, so it's both. For  25 sure, it's a damages issue, but it's also liability. It</p>
<p>1 court yesterday with the FULs.  2       THE COURT: Yes.  3       MR. MERKL: The federal government is the party  4 that sets the FULs. They're the ones, CMS, who looks at all  5 the published data and decides what the FULs should be.  6       In their Medicaid claims, as your Honor knows, the  7 defendants have all asserted, "Well, there's a FUL, there  8 can't be liability," and we're going to have to argue about  9 that, and your Honor has indicated you'll take briefs about  10 that in New York.  11      THE COURT: Right.  12      MR. MERKL: Here in this case, though, since the  13 federal government is CMS and Dey is a party and they're  14 claiming that we somehow did something wrong, it should be  15 incumbent on the federal government to plead, I think, in  16 this pleading how Dey's prices could have affected the FUL.  17 They actually know that because they're CMS. So a complaint  18 that just kind of says, "Well, there's an AWP, and here's the  19 price it could have been bought for on the market," I submit  20 it really doesn't meet 9(b) in that context because they  21 really haven't allowed for or explained the FUL aspect of  22 this. I think they have to account for that.  23      THE COURT: All right, so let me get to them, let  24 them give a full explanation and address the other things. I  25 have been -- I don't remember if any of you were sitting out</p>	<p>1 would be very interesting for me to understand how their  2 prices affected the FUL or what the theory of liability is.  3 Like, I know in multi-source drugs, it's the median of the  4 AWPs in the Medicare context, right?  5        MR. BREEN: Correct.  6        THE COURT: So the argument that's been made, if  7 you had one branded drug case that was accurate, it's the  8 lower of the branded or the generic, and that would pull it  9 down. So, I mean, at least I understand that theory of  10 liability. But if in fact the FUL is on the lowest published  11 price, whatever that means, you would have to allege, I  12 suppose, that Dey's published prices would have been lower  13 than what the FUL was if they were accurate.  14        MR. BREEN: And we have, and, your Honor, from a  15 damages perspective and from a liability --  16        THE COURT: It is liability too. So, I mean, you'd  17 have to allege, have you done this, what their lowest  18 published price should have been?  19        MR. BREEN: Yes. I mean, I think that -- I mean,  20 that arises from our allegations as to what their actual  21 prices were in the marketplace and what their misleading  22 price representations were.  23        THE COURT: When you say "price," as I mentioned  24 yesterday, that's sort of a difficult term in this world. Is  25 it any price, AMP, best price, AWP, WAC, WLP? Or are you</p>

<p style="text-align: right;">Page 34</p> <p>1 looking to a certain category of prices?</p> <p>2 MR. BREEN: When you talk about some of the FULs, 3 the regulation says 150 percent of the lowest published 4 price, and typically -- and there's been testimony by HCFA 5 administrators this week on this issue and the last two 6 weeks.</p> <p>7 THE COURT: I know, but this is -- we've got it, 8 and I don't understand it. I mean, you should at least by 9 briefing supplement and explain your theory of the case with 10 respect to liability. I don't know that I want to go through 11 a whole amended complaint and then motion to dismiss. We 12 could brief this for the rest of our lives. At least explain 13 to me what your theory is and why they're liable. What is 14 the published price? Maybe it's in there. I don't know, 15 these complaints are -- what is the published price that they 16 should have published at that would have brought down the 17 FUL? I mean, that's what you're trying to say?</p> <p>18 MR. MERKL: Yes, how is it that a Dey price caused 19 the FUL to be wrong?</p> <p>20 THE COURT: Well, let's say the FUL is a hundred 21 bucks.</p> <p>22 MR. MERKL: Right.</p> <p>23 THE COURT: And if you had accurately published 24 your price, it would have been fifty bucks, then you are 25 responsible for the higher FUL.</p>	<p style="text-align: right;">Page 36</p> <p>1 paid.</p> <p>2 THE COURT: But in order for them to do something 3 unfair, you have to tell me what it was that was the 4 fraudulent price that would otherwise, if truly reported, 5 have reduced the FUL.</p> <p>6 MR. BREEN: But I'm not saying the FUL would have 7 come down. See, this is the thing, your Honor, where I don't 8 think I'm making myself clear. Each state Medicaid program 9 provides for reimbursement at the lesser of usual and 10 customary, FUL, or the estimated acquisition cost. So if 11 they had reported a false and misleading price --</p> <p>12 THE COURT: All right, did you tell them what that 13 misleading price was?</p> <p>14 MR. BREEN: But it has nothing to do with FUL, is 15 all I'm saying. It's got to do with our allegation that they 16 made a false price representation, because if they made a 17 truthful price representation --</p> <p>18 THE COURT: Well, what was the false price 19 representation?</p> <p>20 MR. BREEN: The false price representation, your 21 Honor, was each and every price that they represented that 22 we've pled in the complaint.</p> <p>23 THE COURT: And did you say what the true price 24 should have been?</p> <p>25 MR. BREEN: Yes. Well, we said the prices they</p>
<p style="text-align: right;">Page 35</p> <p>1 MR. MERKL: Possibly, although they really haven't 2 articulated that.</p> <p>3 THE COURT: Well, maybe. That's what I'm asking 4 them to do.</p> <p>5 MR. MERKL: Yes, and that's what I'm looking for.</p> <p>6 THE COURT: I mean, I want to understand it.</p> <p>7 MR. BREEN: But understand, your Honor, that right 8 now -- and Ven-A-Care has alleged a FUL liability, and I 9 don't even know if the government has intervened on that 10 issue in this case, but let me just explain what I'm saying.</p> <p>11 THE COURT: I assumed they did.</p> <p>12 MS. OBEREMBT: We could construe that as part and 13 parcel of the fraud. And for these drugs, remember, a FUL 14 doesn't get set until there's a number of people out in the 15 marketplace.</p> <p>16 THE COURT: I'm just saying, is that part -- it's 17 part of the government case or -- to be honest, now you've 18 surprised me. I thought everything involving Dey at this 19 point was the U.S.</p> <p>20 MR. BREEN: It is. Judge, it is, and I'm not 21 trying to confuse that issue. All I'm saying is that the way 22 we've pled this, in addition to any impact on the FUL, but 23 the way we've pled this, if their represented prices should 24 have resulted in reimbursement less than the FUL, then the 25 difference is damages between FUL and what should have been</p>	<p style="text-align: right;">Page 37</p> <p>1 pled are false and misleading because they materially exceed 2 and deceptively exceed any price that was available by 3 prudent purchasers in the marketplace, and we put those 4 prices in there.</p> <p>5 THE COURT: You did put those prices in there?</p> <p>6 MR. BREEN: Those are the Ven-A-Care prices, your 7 Honor, that you sustained the New York counties case on.</p> <p>8 THE COURT: All right, so they've done that.</p> <p>9 MS. OBEREMBT: Right.</p> <p>10 MR. BREEN: And, your Honor, this is the critical 11 point: That is the industry insider information that's at 12 the basis of these cases, was at the basis of those OIG 13 reports.</p> <p>14 THE COURT: So then I'm not understanding your 15 point.</p> <p>16 MS. OBEREMBT: Your Honor, our complaint is very 17 similar to the Abbott complaint, which you upheld on 9(b) 18 grounds. We have a similar pricing chart at the end.</p> <p>19 THE COURT: Right. So, candidly, I don't sit and 20 compare and contrast each one of the complaints.</p> <p>21 MR. MERKL: I understand.</p> <p>22 THE COURT: So if they've done that, why isn't that 23 good enough?</p> <p>24 MS. OBEREMBT: They're very similar.</p> <p>25 MR. MERKL: Okay, I'll tell you. What they've pled</p>

<p>1 in the complaint is, they've attached an exhibit. The 2 exhibit gives the Dey AWP, which was set on day one and 3 stayed the same.</p> <p>4 THE COURT: Sure.</p> <p>5 MR. MERKL: And in 2000 and 2001, they pick out a 6 price of a drug that was, I guess, made available to 7 Ven-A-Care at some point, and they put that price, and they 8 say that should be the correct price.</p> <p>9 THE COURT: Okay.</p> <p>10 MR. MERKL: What I've asked your Honor for on the 11 FUL is, fine, that may be one theory that, you know, a FUL 12 was too high because there was other prices out there, 13 notwithstanding that we also reported a WAC that was in 14 between the two that was lower and went down over time. But 15 leaving that aside, given that I do report a WAC which is 16 lower than the FUL and which is different from this, they 17 need to explain, though, how my reporting that AWP impacted 18 on the FUL the federal government set, because if we're 19 paying --</p> <p>20 THE COURT: Why?</p> <p>21 MR. MERKL: Pardon me?</p> <p>22 THE COURT: All right, you know what, I need to -- 23 I don't know -- let me put it this way: You're going to 24 explain your theory in a supplemental brief. How long do you 25 want?</p>	<p>Page 38</p> <p>1 THE COURT: I've got a sentencing. I've got to get 2 moving.</p> <p>3 MR. BREEN: Your Honor, we're prepared to proceed.</p> <p>4 THE COURT: Okay, go ahead.</p> <p>5 MS. OBEREMBT: Your Honor, luckily one of my 6 colleagues, I think, is an expert on the FUL, and I will 7 gratefully tell him to please start drafting, and we'll 8 explain that.</p> <p>9 With respect to the statute of limitations, I 10 really could not disagree more with Mr. Merkl's argument 11 there. Notwithstanding any Senate report, I think the False 12 Claims Act is really clear that the statute is tolled once a 13 relator brings an action. The language of the statute 14 indicates in the statute --</p> <p>15 THE COURT: But it's only tolled with respect to 16 the claims that were filed, not some new claims.</p> <p>17 MS. OBEREMBT: Well, it's tolled with respect to 18 the claims that were filed, and also that Rule 15 permits us 19 to relate back to those claims.</p> <p>20 THE COURT: Take an extreme law school example. 21 Suppose the initial related claim was against Abbott.</p> <p>22 MS. OBEREMBT: Right.</p> <p>23 THE COURT: And three years later you amend it to 24 add Dey. You couldn't say the thing against Dey related back 25 to the thing against Abbott.</p>
<p>Page 39</p> <p>1 MR. BREEN: Your Honor, we'd be happy to. 2 Thirty days?</p> <p>3 THE COURT: Just to make sure I understand it. FUL 4 has been a thorn in my side on this. I find it very 5 difficult to follow. When they say "published price," I 6 don't know what that means. I've seen these books, and they 7 publish AWP, they publish WACs sometimes, and they publish 8 something called direct price, and they publish something 9 called wholesale list price. Is that the published prices 10 we're talking about, or does it drop yet again to other 11 prices like AMPs or best prices?</p> <p>12 MR. BREEN: No. Your Honor --</p> <p>13 THE COURT: So you need to explain it to me.</p> <p>14 MR. BREEN: Absolutely not. AMP and best price, we 15 will explain it in a supplemental brief, your Honor.</p> <p>16 THE COURT: I don't even know what "published" 17 means, so you've got to explain what it is that they should 18 have published that they didn't.</p> <p>19 MR. BREEN: Yes, your Honor.</p> <p>20 THE COURT: I'm not going to do the motion to 21 dismiss route on it. But let's get to statute of 22 limitations, which is really -- I have other hearings, and I 23 need to just get on it.</p> <p>24 MR. BREEN: All right, and if you want to hear 25 about the state bar --</p>	<p>Page 41</p> <p>1 MS. OBEREMBT: Absolutely not, your Honor.</p> <p>2 THE COURT: Okay, so we're at least in the same 3 ballpark. When there's a new defendant and a new drug, let's 4 say, it's got to start from when that was first in the 5 complaint.</p> <p>6 MS. OBEREMBT: I would actually separate out the 7 issue of new defendant versus new drug. I think the scheme 8 here is one that cuts across many drugs in a company. We 9 don't view each drug as an isolated scheme. You have the 10 same actors involved. It's the same conduct. They see a 11 profit opportunity with another drug, and they begin 12 inflating the AWPs, and they begin doing the other conduct 13 with respect to that drug. So I don't think adding drugs is 14 a significant amendment here.</p> <p>15 THE COURT: You know, I'm a little -- I'm very 16 steeped in this right now, okay? And so what I've learned is 17 that it actually sometimes is the same scheme, and sometimes 18 it's very different, depending on whether it's 19 self-administered or physician-administered, or generic or 20 branded multi-source, or distributed through different 21 classes of trade. In other words, it's an incredibly 22 complicated world, so wouldn't I have to figure it out drug 23 by drug as to whether it was the same transaction, scheme, 24 occurrence, et cetera?</p> <p>25 MS. OBEREMBT: I think, with respect to Dey, you</p>

<p>1 would not have those concerns.</p> <p>2 THE COURT: Because they're all what, generics?</p> <p>3 MS. OBEREMBT: They were all generics. It is a</p> <p>4 small tight-knit company. You're talking about a core group</p> <p>5 of people making the decisions who could probably fit around</p> <p>6 this table fairly easily, so we don't have a sprawling</p> <p>7 defendant.</p> <p>8 THE COURT: So, for example, with Schering-Plough,</p> <p>9 by the way, the albuterol starts off branded and then ends up</p> <p>10 generic, and it's very different. Just it's different in how</p> <p>11 the whole thing historically went down. So you're saying I</p> <p>12 don't have those kinds of problems in Dey?</p> <p>13 MS. OBEREMBT: No, you don't, your Honor. You</p> <p>14 don't. And I think, getting back to the language of the</p> <p>15 statute, which has to be the touchstone for deciding the</p> <p>16 statute of limitations issue, I think the most common sense</p> <p>17 approach, which is the one that has been followed by the</p> <p>18 majority of District Courts -- I mean, the Second Circuit</p> <p>19 decision really came out of the blue in many respects, and I</p> <p>20 think it's wrongly decided --</p> <p>21 THE COURT: Was there a petition for remand</p> <p>22 en banc?</p> <p>23 MS. OBEREMBT: No, I don't believe there was, but</p> <p>24 there was a companion case to the Baylor case. The Baylor</p> <p>25 case turned on the enforcement of a manual provision</p>	<p>Page 42</p> <p>1 stop this whole case because there's too many cases. I'm</p> <p>2 just wondering, does it make sense to certify that issue to</p> <p>3 the First Circuit?</p> <p>4 MR. MERKL: Well, we were hoping it would go up on</p> <p>5 appeal as a right, but we think that we can. We are looking</p> <p>6 at it. I haven't --</p> <p>7 THE COURT: I'm not knocking out this whole suit.</p> <p>8 MR. MERKL: I understand that.</p> <p>9 THE COURT: I mean, so at best you get back to</p> <p>10 2000, so is it worth it?</p> <p>11 MR. MERKL: We think you can, but I guess I have to</p> <p>12 finish that research before I could make it.</p> <p>13 MR. BREEN: Your Honor, I think that the problem</p> <p>14 with that is, it's so fact-specific, and I think that's the</p> <p>15 thing -- there's a couple assumptions I think being made here</p> <p>16 that aren't necessarily correct as to the relationship</p> <p>17 between the facts in this case and perhaps the Kosnos (Phon)</p> <p>18 case. Number one -- I hate to be hypertechnical, but it's a</p> <p>19 hypertechnical decision. Number one, the relator's</p> <p>20 complaint -- let's assume that these drugs that were pled in</p> <p>21 the 2000 Boston case should have been part of the first</p> <p>22 case. Well, the first case and the second case were</p> <p>23 consolidated here in Boston before it was unsealed, and then</p> <p>24 the relator amended again. So if it was a second-to-file</p> <p>25 issue, then the relator could have amended and added those</p>
<p>Page 43</p> <p>1 concerning the reimbursement of investigative cardiac</p> <p>2 devices. The companion decision held that the manual</p> <p>3 provision was not promulgated in accord with the APA. So I</p> <p>4 think the decision to seek hearing was probably complicated</p> <p>5 as opposed to --</p> <p>6 THE COURT: That's the killer case for you.</p> <p>7 MS. OBEREMBT: Oh, believe me, we're --</p> <p>8 THE COURT: You're in appeal, you didn't go</p> <p>9 petition for rehearing. You know, the First Circuit likes</p> <p>10 the Second Circuit. They're all up and down the same</p> <p>11 corridor. I mean, it's not like some other part of the</p> <p>12 country. So that's a very serious case that I need to think</p> <p>13 about.</p> <p>14 MS. OBEREMBT: We are taking it seriously, but we</p> <p>15 do believe that it was wrongly decided. And we believe when</p> <p>16 you look at the statute, it makes sense to have the relator's</p> <p>17 complaint toll the statute of limitations. And in this case,</p> <p>18 there's really -- they've not disputed that the facts in the</p> <p>19 complaint in intervention relate back for factual purposes to</p> <p>20 the complaint pled by the relator. That's not really an</p> <p>21 issue here.</p> <p>22 THE COURT: Let me ask you this. It's really a</p> <p>23 cutting-edge issue, and it will not eliminate this suit, and</p> <p>24 so it will continue along. Is there any way to certify that</p> <p>25 to the First Circuit? In other words, I wouldn't want to</p>	<p>Page 45</p> <p>1 drugs because it was the same broad scheme. And so it did.</p> <p>2 It's the same complaint. So its '97 complaint was</p> <p>3 consolidated with the 2000 complaint, and then there was an</p> <p>4 amendment.</p> <p>5 Now, here's the other thing that's very important.</p> <p>6 When the government prepared their complaint in intervention,</p> <p>7 the relator amended to join that complaint. So the</p> <p>8 government's complaint in intervention and the relator's</p> <p>9 existing live amended complaint are the same pleading. And I</p> <p>10 think that's very important. Unlike Kosnos (Phon) where the</p> <p>11 government had a separate claim, there's a straight line of</p> <p>12 complaints that the relator filed going back to its original</p> <p>13 1997 complaint on the same fraud scheme, which it brought to</p> <p>14 the attention of the OIG and it brought to the attention of</p> <p>15 the government and the Congress. So it goes all the way back</p> <p>16 to that point in time. It's a frozen rope right back through</p> <p>17 those pleadings where the relator disclosed this fraud</p> <p>18 scheme, went to the OIG, pled it, and then added some drugs</p> <p>19 in Boston in 2000, but those two complaints were pled</p> <p>20 together.</p> <p>21 THE COURT: Well, why did you do that in Boston?</p> <p>22 MR. BREEN: Well, your Honor, there's a lot of</p> <p>23 factors here. There were a lot of defendants. Just a lot of</p> <p>24 things were going on. The effort that it took for the</p> <p>25 relator and its limited legal resources to marshal this case</p>

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1 and marshal this information, and the complexion it took once  
 2 the judges in Miami said, "Go out and pursue the state  
 3 cases," one of which was against Dey Laboratories, and  
 4 they've had every one of their witnesses deposed in the 2000  
 5 Texas case, so it's just been a monster, is the best way I  
 6 can describe it.

7 THE COURT: But the government is doing it now, so  
 8 I don't even know why you're standing. No, I'm serious  
 9 here. I mean, you're in control of this case now, right?  
 10 It's only your case?

11 MS. OBEREMBT: Right. And I think, focusing back  
 12 on your issue about having this issue go up to the First  
 13 Circuit, the Second Circuit did not consider relation back  
 14 under Rule 15(c)(1).

15 THE COURT: Right.

16 MS. OBEREMBT: They said it was a colorable  
 17 argument, but it wasn't presented to them. And I think your  
 18 Honor could rule in our favor with respect to 15(c)(1). I  
 19 believe it would make sense here given the statute. The way  
 20 the statute is written, I believe it definitely provides for  
 21 the tolling once the relator's complaint has been filed.

22 THE COURT: And you would say forever? In other  
 23 words, this is a pretty extreme example.

24 MS. OBEREMBT: Well, your Honor, the statute  
 25 provides that the District Court judge is the bulwark against

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1 constitutional. Statute of limitations are construed very  
 2 narrowly against the government, and the Supreme Court has  
 3 recently upheld that principle yet again. I mean,  
 4 notwithstanding the concerns about passage of time,  
 5 et cetera, those aren't valid reasons to put in place a  
 6 statute of limitations against the government that doesn't  
 7 exist, that Congress didn't give it.

8 THE COURT: Under 15(a), you know, motions to amend  
 9 must be liberally construed, and one of the things you think  
 10 about is prejudice to the defendants. It just seems like  
 11 that's being ruled out of this.

12 MS. OBEREMBT: I think also the facts in this  
 13 particular case don't lend themselves to a prejudice  
 14 argument. Dey received a subpoena within several months of  
 15 the first complaint being filed in Florida. They received  
 16 several subpoenas thereafter. The department obtained a  
 17 partial list and disclosed the allegations to them I believe  
 18 as early as 1998. They've been on notice for many years  
 19 about the issues. They've had lengthy discussions with the  
 20 department.

21 THE COURT: Sure, but what about his point that you  
 22 can't -- I've actually had this debate with some members of  
 23 my local U.S. Attorney's office: What about witness  
 24 memories? People forget. Documents get lost, right?

25 MS. OBEREMBT: Well, that's a risk in any case with

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1 cases going on forever, and you yourself have pointed out  
 2 that you ask lawyers questions about these cases, that you  
 3 don't let them go on forever. You're not alone in that  
 4 approach. Congress specifically provided that we didn't have  
 5 the right to have unlimited amounts of time. We have to  
 6 report to a District Court judge, and we have to demonstrate  
 7 good cause for whatever it is we do.

8 THE COURT: At some point, though, at the end of  
 9 the day, it's ex parte.

10 MS. OBEREMBT: It is, absolutely.

11 THE COURT: So you're a busy judge, and I sort of  
 12 allow, you know, a certain number of free bites at the apple,  
 13 and then I start reeling people in and saying, you know, "No  
 14 more extensions after this date." And then you get these  
 15 screams of, "You don't know, Judge, how many thousands of  
 16 documents, and I can't possibly get through these," and then  
 17 you take pity and give them another extension. But that's  
 18 all without them having a chance to know what's going on, and  
 19 at some point, isn't there some due process concern if it  
 20 goes on and on and on?

21 MS. OBEREMBT: You know, your Honor, I think we  
 22 could all come up with a hypothetical where at the end of the  
 23 day, we felt, my gosh, this might rise to the level of due  
 24 process. You know, Congress could have passed the statute  
 25 without any statute of limitations, and it would have been

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1 the passage of time. The False Claims Act permits --  
 2 THE COURT: But don't they bear the brunt of it,  
 3 though, a bit?

4 MS. OBEREMBT: They do in some respects, but the  
 5 statute itself permits us to go back a full ten years under  
 6 the three-year provision that they're relying on.

7 THE COURT: Nine years, right?

8 MS. OBEREMBT: No. It's ten years from the date  
 9 that -- if we file suit within three years after we knew or  
 10 should have known, we're allowed to go back for claims dating  
 11 back ten years. So Congress contemplated --

12 THE COURT: Well, where did I get six years?

13 MS. OBEREMBT: There are two provisions in the  
 14 statute, the six-year one which we contend is tolled once the  
 15 relator's complaint is filed. There's also one which we  
 16 believe was envisioned to encompass situations where an  
 17 informant comes in, does not file a lawsuit, so there's no  
 18 District Court judge overseeing anything. An informant comes  
 19 in, provides us with information, and then we have three  
 20 years from the date that we knew or should have known the  
 21 information, and we're allowed to go back ten years. So  
 22 Congress envisioned --

23 THE COURT: So that doesn't apply to me here.

24 MS. OBEREMBT: In this case, because the relator  
 25 filed suit. But my point is, Congress envisioned that these

<p>1 cases might take a very long time.  2 THE COURT: Okay, well, this is a very, very  3 difficult issue.  4 MR. MERKL: Your Honor, on the certification point,  5 Baylor was certified. So I think we certainly could do that  6 here, and that is something we will do.  7 THE COURT: What did the trial court judge do  8 there? He denied the motion to dismiss?  9 MR. MERKL: Exactly. I believe it was a cardiac  10 devices case below. I might have it wrong.  11 THE COURT: Did that knock out the whole case? The  12 difference here is, I have to tell you, you've got still six  13 years of liability.  14 MR. MERKL: Yes, I'm not sure if in Baylor it would  15 have ended the whole suit, but I do know the defendant lost  16 in the District Court, and that in the decision itself, it  17 says the appeal was by permission, not as a right.  18 THE COURT: So if the government files in 2000,  19 right --  20 MR. MERKL: In Baylor?  21 THE COURT: -- in this case in 2006, it gets back  22 to 2000, right? He can collect legitimately back to 2000?  23 MR. MERKL: Yes, under what your Honor ruled  24 earlier, yes.  25 THE COURT: So I'm just thinking, is it worth it</p>	<p>Page 50</p> <p>1 MS. OBEREMBT: Well, your Honor, the big picture --  2 THE COURT: How many defendants are we looking at?  3 MS. OBEREMBT: Your Honor, I wouldn't be at liberty  4 to disclose that.  5 THE COURT: Are we looking at more than Roxane?  6 You can disclose it. You don't have to tell me who. How  7 many are we talking about, just ballpark?  8 MS. OBEREMBT: Your Honor, I really have no  9 authority to provide that because we require a decision to  10 file suit. And let me put it this way: We have not  11 obtained -- well, I can't even say that actually, your  12 Honor.  13 THE COURT: You put me in a bad spot staffingwise  14 because in order for me to put in for a third law clerk, I  15 have to know what's happening. And so every time I think  16 I've finished another one of these monsters, another one is  17 filed. And, as you know, it's by no means the only set that  18 I have. And so if I'm looking at another fifty of these, I  19 need to know this.  20 MS. OBEREMBT: No, it is not another fifty.  21 THE COURT: Greater than five, less than ten?  22 (Laughter.)  23 THE COURT: I tell you what, file within a week  24 in camera, nonbinding, what you think I'm going to be looking  25 at if you were looking in a crystal ball.</p>
<p>1 for the extra --  2 MR. MERKL: But I think in this case, your Honor,  3 it definitely is because most of the conduct and most of the  4 liability is all pre-2000 liability.  5 THE COURT: I have these other cases. I mean, it's  6 very, very well briefed, and it's very -- actually it's an  7 interesting issue. It shows you how warped you get.  8 (Laughter.)  9 THE COURT: But let me ask you this: Do you have a  10 discovery schedule?  11 MS. OBEREMBT: We're actually working on that right  12 now, your Honor, and we should have a proposed case  13 management order issue probably within the next two weeks.  14 THE COURT: All right, within two weeks get that to  15 me. Are you coordinating with the other cases?  16 MR. MERKL: Yes, your Honor.  17 MS. OBEREMBT: Yes.  18 THE COURT: And this is killing me, it's coming in  19 in dribs and drabs. I mean, how many other defendants are  20 out there in the wings?  21 MS. OBEREMBT: Well, the next motion to dismiss  22 hearing that you have set is with Roxane, your Honor.  23 THE COURT: I'm just one judge here, all right? So  24 what's happening here? What's the big picture? I need to do  25 this for staffing reasons.</p>	<p>Page 51</p> <p>1 MR. BREEN: You want the relator also, your Honor,  2 or merely the government on that?  3 THE COURT: Ah-hah, another country speaks. So if  4 they decline to intervene, you might bring them anyway?  5 MR. BREEN: Your Honor, it's very difficult for me  6 to respond to that question in open court. And, your Honor,  7 it's complicated, as your Honor has noted, it's very  8 complicated, and I can't respond directly to your Honor's  9 question in open court. I think I'd be violating --  10 THE COURT: So give me something in camera. I just  11 want to understand staffingwise so come September I know what  12 I have. I've got Track 2 in the AWP.  13 MS. OBEREMBT: Right.  14 THE COURT: Hopefully by then I will be done one  15 way or another with the first track. I've tried the last --  16 well, I may have one more trial. But, in any event, I'll be  17 close to being done on the AWP, right? And so I've got that,  18 and then I've got a ton of state Attorney General suits. I  19 now have at least twelve motions to remand, and I've got the  20 county suits in New York. So I just need to have some --  21 every one of these raises a new and important point. This is  22 statute of limitations. The last one was what I do with  23 multi-source and Medicaid.  24 By the way, am I right that there's no express  25 certificate in Medicaid for any of the states?</p>

<p>1 MS. OBEREMBT: What there is is an implied 2 certification, your Honor, and actually I was -- 3 THE COURT: But that's a misnomer because almost 4 every case that says "implied certification" actually has a 5 certificate. 6 MS. OBEREMBT: Actually, your Honor, there's 7 another District Court case that has held that a claim to 8 Medicaid contains an implied certification of compliance with 9 the Anti-Kickback Statute. It's United States V. Rogan, and 10 it's cited in our Roxane pleadings, the Northern District of 11 Illinois. 12 THE COURT: And that's basically what I have. 13 MS. OBEREMBT: Yes. 14 THE COURT: I'm simply saying, I didn't have that 15 case, and I didn't even know whether there were certificates 16 factually. In Medicare there's certificates, right? There's 17 actually a certification: "I comply with the anti-kickback 18 rules"? 19 MS. OBEREMBT: Well, let me take five minutes, and 20 I can explain that to you pretty quickly. Medicare cost 21 reports that hospitals file contain explicit certification of 22 compliance with the Anti-Kickback Statute. The specific 23 patient claims and the types of claims we have here do not 24 contain that explicit certification of compliance with the 25 Anti-Kickback Statute. But as you've held and other courts</p>	<p>1 in a nonmulti-source arena, publishing a false AWP is 2 remuneration for purposes of the kickback scheme. I haven't 3 even touched that one yet. So it's not like I can simply say 4 "Denied" or "Allowed, see X." I'm actually working through 5 them, and so it's useful for me to know what my work load is 6 going to look like for the coming year. 7 MS. OBEREMBT: So just so I'm clear on what you 8 would like us to do, within a week, you would like a 9 nonbinding in camera, and I assume, of course, ex parte -- 10 THE COURT: Yes. 11 MS. OBEREMBT: -- statement of what we believe our 12 intentions are for what period of time? You mentioned 13 September. Would you like -- 14 THE COURT: No, just basically, what do I expect 15 from both of you over the next year so I can decide what kind 16 of a staffing and how to allocate staffing. That's just 17 important on these cases. 18 The second is, you're going to disclose to them all 19 the sealed documents except with respect to anything that 20 would disclose a criminal investigation or something that 21 might jeopardize somebody's life or something like that. 22 MS. OBEREMBT: Right. Well, I think that issue is 23 going to be before you with respect to the Abbott case and 24 whatever flows out of that. 25 THE COURT: Well, whatever you know you can turn</p>
<p>1 have held, compliance with the Anti-Kickback Statute is a 2 condition of payment, and therefore, if you submit a claim, 3 you impliedly certify compliance with that. On the Medicaid 4 side, it varies state by state because every state has 5 different claim forms. 6 THE COURT: So some have express certifications, 7 and some are implied. I'm simply saying it's not been well 8 laid out for me factually -- 9 MS. OBEREMBT: Right, and I think it's very 10 difficult because -- 11 THE COURT: -- what happens. And also, even under 12 Medicare, you just taught me something right now that I 13 didn't know because it wasn't pled that way, as to which 14 classes of trade have to certify and which ones don't. It's 15 almost never laid out that clearly. 16 MS. OBEREMBT: Right. And the other example is in 17 the McNutt case, the Eleventh Circuit case that you cited -- 18 THE COURT: That's a problem case because there was 19 in fact an express certification, but the dicta speaks louder 20 than that. So I don't want to get into it now. I've ruled 21 the way I have. I am simply making the point that you assume 22 a fair amount of knowledge sometimes -- maybe you don't have 23 the knowledge or maybe you assume I know it, I don't know -- 24 that every case is involving some big new issue. I haven't 25 even dealt with the hardest one yet, okay, which is whether</p>	<p>1 over, turn over. Whatever is in question, you'll bring it to 2 me. You're going to supplement with respect to FUL, and were 3 you going to do anything? 4 MR. MERKL: No, your Honor. Well -- 5 THE COURT: Oh, yes, you wanted to look into the 6 interlocutory -- 7 MR. MERKL: Certify the appeal, we will do that, 8 and we will get your Honor something in writing on that. 9 Thank you, your Honor. 10 THE COURT: I have two more criminal things I just 11 have to go to. Thank you very much. 12 MS. OBEREMBT: Thank you, your Honor. 13 MR. MERKL: Thank you, your Honor. 14 (Adjourned, 3:45 p.m.) 15 16 17 18 19 20 21 22 23 24 25</p>

1 C E R T I F I C A T E  
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UNITED STATES DISTRICT COURT )  
DISTRICT OF MASSACHUSETTS ) ss.  
CITY OF BOSTON )

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8 Lee A. Marzilli, Official Federal Court  
9 Reporter, do hereby certify that the foregoing transcript,  
10 Pages 1 through 57 inclusive, was recorded by me  
11 stenographically at the time and place aforesaid in Civil  
12 Action No. 01-12257-PBS, MDL No. 1456, In re: Pharmaceutical  
13 Industry Average Wholesale Price Litigation, and thereafter  
14 by me reduced to typewriting and is a true and accurate  
15 record of the proceedings.

16 In witness whereof I have hereunto set my hand this  
17 23rd day of May, 2007.

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23  
24 LEE A. MARZILLI, CRR  
25 OFFICIAL FEDERAL COURT REPORTER

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